Filing Date: May 13, 2002 Examiner: Randall O. Winston; Art Unit: 1654 Attorney Docket No. 06-503/von Kreisler.018

III. REMARKS

A. Rejection Under 35 U.S.C. §103

Claims 1-6, 8-13, 15-19 and 22-31 are rejected under 35 U.S.C. §103 as being unpatentable over United States Patent No. 5,591,395 to Schroeder et al. in view of United States Patent No. 5,569,461 to Andrews ("Andrews"), ("Antimicrobial Properties of Tannins," Phytochemistry Vol. 30, No. 12, pp. 3875–3883, 1991), Varga, J. (Derwent ACC-NO 1976-72203X (see Abstract) ("Varga Abstract"), United States Patent No. 4,110,430 to Hopp et al. ("Hopp et al."), United States Patent No. 6,033,705 to Isaacs ("Isaacs") and United States Patent No. 6,284,259 to Beerse et al. ("Beerse et al.").

1. Examiner's Reasons in Support of the Rejection

The Examiner's reasons in support of the rejection are as follows:

[Applicant] daims a method for disinfection of air to reduce the concentration of germs comprising the distributing or atomizing of an antimicrobial composition wherein the antimicrobial composition is free from ethanol and isopropanol and wherein the antimicrobial composition comprises propylene glycol, tannins, lactic acid, benzyl alcohol and further comprises hydrocinnamic alcohol, additional GRAS flavoring agents such as essential oils (see, e.g. claims 10 and 31) and an emulsifier (see, e.g. claim 17).

Schroeder et al. teach (see, e.g., Abstract, column 1, lines 54-67) an antimicrobial and/aor antibacterial composition comprising propylene glycol for disinfecting the air of bacteria. Schroeder does not teach the other claimed active ingredient such as lactic acid, tannins, a benzyl alcohol, a hydrocinnamic alcohol, additional GRAS flavoring agents such as essential oils and an emulsifier contained within its antimicrobial composition. Andrews beneficially teaches (see, e.g., claims) lactic acid and propylene glycol to have antimicrobial and/or antibacterial properties.

Scalbert et al. beneficially teach (see, e.g. entire article) tannins to have antimicrobial properties.

Varga J beneficially teaches (see, e.g. abstract) a benzyl alcohol to have antimicrobial and/or antibacterial properties.

Hopp et al. beneficially teach (see, e.g., column 1, lines 21-29 and lines 60-65) a hydrocinnamic alcohol to have antimicrobial and/or antibacterial properties.

Isaacs beneficially [teaches] (see, e.g., column 10, lines 23–29) an emulsifier may be added to a compound to enhance its antimicrobial effect.

Beerse et al. beneficially teach (see, e.g. column 9, lines 19–39) essential oils to have antimicrobial and/or antibacterial properties.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Schroeder's antimicrobial composition to include the other claimed active ingredients beneficially taught by Andrews, Scalbert, Varga J, Hopp, Isaacs and Beerse because the combined above references would create an improved claimed antimicrobial composition wherein the improved claimed composition would intrinsically disinfect the air when reducing the concentration of microbial and/or bacteria germs within the air. Furthermore, the adjustment of other conventional working conditions (e.g. the claimed concentrations of the antimicrobial composition within the air, the type of antimicrobial system and/or spray design and the substitution of known bacteria for one another to be treated and/or reduced), is deemed merely a matter of judicious

selection and routine optimization which is well within the purview of the skilled artisan.

Accordingly, the claimed invention was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

(Action, page 2, line 19 to page 4, line 11).

2. Comparison of Claimed Invention and Prior Art

Independent claims 1 and 22 are directed to a method and composition for the disinfection of air comprising the distributing or atomizing of an antimicrobial composition that can be added to the air to achieve a dosage of from 0.001 to 1 ml per cubic meter of air per hour. The claims also are directed to the achievement of a permanent concentration of from 5 to 10 ptb (parts per billion) of the antimicrobial composition in the air. The antimicrobial composition is free from ethanol and isopropanol and comprises propylene glycol, tannins and lactic acid. Independent claims 23, 25 and 27 are also directed to the above-referenced method, except that disinfection of air is further defined as reducing the concentration of germs selected from gram-positive bacteria, gram-negative bacteria, molds, spore-formers, viruses, bacillus subtilis, pseudomona fluorescene, staphylococcus aureus, aspergillus niger, hepatitis B and bactillis anthracis. The remaining claims 2-6, 8-13, 15-19, 24, 26 and 28-31 are dependent upon the above-referenced independent claims or are dependent upon a claim that in turn is dependent upon one of the above-referenced independent claims.

Applicant's claimed antimicrobial composition which comprises propylene glycol in combination with tannins (i.e., tannic acid) and/or lactic acid is unexpectedly superior as an antimicrobial composition than propylene glycol alone. Because of this unexpected superiority, Applicant's claimed method utilizes an antimicrobial composition in extremely low concentrations in air, namely, 5 to 10 parts per billion. None of the prior art references relied on by the Examiner discloses, exemplifies or even suggests to one of ordinary skill in the art a method using antimicrobial compositions in such low concentrations.

Schroeder et al. discloses a method of disinfecting the air and killing airborne bacteria, etc. by creating particles of disinfecting compounds using a heated wick. As acknowledged by the Examiner, the Schroeder et al. composition comprises propylene glycol and not the combination of propylene glycol with tannins and/or lactic acid disclosed and claimed by Applicant. As noted above, a low concentration of Applicant's claimed composition is due to the extraordinary effectiveness as an antimicrobial composition of a combination of propylene glycol and tannins and/or lactic acid. This extraordinary effectiveness is not shared by compositions comprising propylene glycol alone. Schroeder et al. does not disclose the concentrations in which the Schroeder et al. composition is used in air. However, given the much lower effectiveness of propylene glycol as an antimicrobial, the concentrations in air of the disinfecting compounds being employed by Schroeder et al. must be much higher than Applicant's claimed concentration.

Andrews is directed to a topical composition and related method for disinfecting, cleaning, conditioning and treating skin using a propylene glycol monoester and capric or caprylic acid, a second propylene glycol monoester of capric and/or caprylic acid, a synergist, propylene glycol, a surfactant and a vehicle (Abstract). The Andrews antimicrobial compositions are disclosed as useful when applied to the teats and udders of dairy animals as udder and teat washes and as pre-milking teat skin sanitizing solutions (pre-dips). (Column 2, lines 7–12). Accordingly, the Andrews compositions are used as a liquid. Andrews does not exemplify or otherwise disclose to one of ordinary skill in the art the concentrations in air in which the Andrews antimicrobial compositions should be employed.

Scalbert reviews data on tannin toxicity against fungi, bacteria and yeasts and compared to toxicity of related lower molecular weight phenols (Abstract). Examples of tannin toxicity disclosed in Scalbert involve concentrations of tannin that are higher by many magnitudes than the concentration disclosed in Applicant's claims. In Scalbert, tannin concentrations vary from 0.063 gram per liter to 100 grams per liter. (See page 3878, lines 29–44 and page 3880, last paragraph). A concentration of 0.063 grams per liter, which is described in Scalbert as "a low tannin concentration" is equivalent to a concentration of about 1 part per 16,000 parts of composition. In contrast, Applicant's claims are limited to concentrations in air of from 5 to 10 parts per billion, or about 6,000 times lower than the lowest tannin concentration disclosed in Scalbert. From the range of concentrations given for tannins in Scalbert and the expression of concentration in grams per

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liter, it appears that the Scalbert composition is in liquid form and not intended to be used in air. As noted above, Scalbert does not disclose any concentrations in air at which the Scalbert composition is intended to exist, let alone the concentrations of antimicrobial composition in the air set forth in Applicant's claimed method.

The Varga Abstract discloses treatment of the surface of a doormat with the combination of methylparaban, propylparaban and benzyl alcohol to disinfect it and destroy bacteria, fungi, and viruses deposited on the mat. It appears that the Varga composition is in liquid form and is not intended to be present in the air. Varga does not disclose any concentrations in air at which the Varga composition is intended to exist, let alone the concentrations of antimicrobial composition in the air set forth in Applicant's claimed method.

Hopp et al. is directed to a germ-inhibiting, microbicidal or deodorizing composition comprising p-isopropyl-and/or p-tert.butyl-alpha-methyl hydrocinnamic alcohol, together with a carrier or dilutant (Abstract). The Hopp et al. composition appears to be in the form of a liquid or spray. Hopp et al. discloses that "the germ-inhibiting microbicidal properties of the hydrocinnamic alcohols to be used according to the invention become apparent when these compounds are applied in an amount of at least 0.001 mg per cm² of skin. (Column 1 lines 61–64). Such concentrations appear to be several orders of magnitude greater than the concentration of antimicrobial composition in air set forth in Applicant's claimed method. No other concentrations of the composition are disclosed.

The final two references, Isaacs and Beerse et al. relate to treatments of a surface with an antimicrobial liquid. Isaacs is directed to a process for inhibiting microbial growth on a surface of an edible foodstuff, which comprises applying to the surface a defined compound selected from a group consisting of certain fatty acids and derivatives of fatty acids and fatty alcohols (Abstract). Beerse et al. relates to an antimicrobial wipe comprising a porous or absorbent sheet impregnated with an antimicrobial cleansing composition, wherein the antimicrobial cleansing composition comprises from about 0.001% to about 5.0% by weight of the antimicrobial cleansing composition of an antimicrobial active. Neither Isaacs nor Beerse et al. discloses a method which involves the achievement of a concentration in air of from 5 to 10 parts per billion of the antimicrobial composition.

3. No prima facie case of obviousness

Section 2141 of the *Manual of Patent Examining Procedure* sets forth the following basis determining whether Applicant's claimed method is obvious over the art relied on for the pending rejection of the claims:

MPEP Section 2141 then recites a number of exemplary rationales that may support a conclusion of obviousness.

The rationale most pertinent to the comparison between Applicant's claimed method the combination of references cited in rejection of the claims is rationale (A) "combining prior art elements according to known methods to yield predictable results."

No prima facie case of obviousness has been made because the prior art references, when combined, do not teach or suggest all of Applicant's claimed limitations, in particular, Applicant's claimed microbial composition comprising propylene glycol in combination with tannins (i.e., tannic acid) and/or lactic acid and a concentration in air of from five to ten parts per billion of the antimicrobial composition. Instead, the prior art relied on by the Examiner employs concentrations of compositions that are many orders of magnitude greater than Applicant's claimed composition. Accordingly, the prior art does not satisfy the criteria that the teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art.

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The Examiner suggests that the modification of the prior art is merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan. In fact, the prior art relied on by the Examiner cannot be so modified. As noted above, Scalbert discloses a range of concentrations of tannins over 6,000 times the concentration of the composition set forth in Applicant's claims. The Scalbert article focuses on tannin toxicity and the concentration of tannins required to achieve toxicity for fungi, bacteria and yeasts. The Scalbert article discloses that even at one hundred grams per liter, certain species of penicillium and aspergillus still achieve good growth (p. 3880). This disclosure suggests that the much lower concentrations of tannins set forth in Applicant's claims would be less effective, not more. If the proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. In re Gordon, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984).

In addition, as noted above, Scalbert and the other references are not directed to a method using antimicrobial compositions in very low concentrations in air. Indeed, the concentrations proposed in Scalbert are not applicable to a method of disinfection in air. If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims prima facie obvious. In re Ratti, 270 F.2d 810, 123 USPQ 349 (CCPA 1959).

For the reasons set forth above, one skilled in the art cannot derive from the combination of references relied on by the Examiner how to obtain Applicant's claimed method. Nor are the limitations as to air concentration in Applicant's claimed method merely a matter of judicious selection and routine observation which is well within the purview of the skilled artisan. Instead, the discovery of an antimicrobial composition that can be employed at the very low concentration levels set forth in Applicant's claims is itself patentable absent the disclosure of that feature of the invention in the art. Accordingly, the rejection of claims 1–6, 8–13, 15–19 and 22–31 under 35 U.S.C. \$103 is untenable and should be withdrawn for the reasons set forth above.

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IV. Conclusion

It is believed that the above Amendment and Remarks constitute a complete response under 37 CFR §1.111 and that all bases of rejection in the Examiner's Action have been adequately rebutted or overcome. A Notice of Allowance in the next Office Action is, therefore, respectfully requested. The Examiner is requested to telephone the undersigned attorney if any matter that can be expected to be resolved in a telephone interview is believed to impede the allowance of pending claims 1–6, 8–13, 15–19 and 22–31 of United States Patent Application Serial No. 10/019,240.

Respectfully submitted,

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